



State of New Jersey

DEPARTMENT OF HEALTH AND SENIOR SERVICES

PO BOX 367
TRENTON, N.J. 08625-0367

www.nj.gov/health

RICHARD J. CODEY
Acting Governor

FRED M. JACOBS, M.D., J.D.
Commissioner

To: All Administrators of Long-Term Care Facilities

From: Barbara Goldman, R.N., J.D.
Director
Long-Term Care Licensing and Certification

Date: November 22, 2005

Subject: Adopted Amendment and Rule at N.J.A.C. 8:39 - Standards for Licensure of Long-Term Care Facilities

I am writing to inform you that the Department has adopted an amendment of N.J.A.C. 8:39-1.2 and a new rule at N.J.A.C. 8:39-23.3. The notice of adoption was published in the New Jersey Register on November 21, 2005 at 37 N.J.R. 4437(a).

The adopted amendment and new rule implement the statutory requirement for long-term care facilities to acquire, train their staff in the use of, and maintain a defibrillator.

A copy of the above referenced notice of adoption follows.

HEALTH AND SENIOR SERVICES

SENIOR SERVICES BRANCH

DIVISION OF LONG-TERM CARE SYSTEMS

Adopted Amendment: N.J.A.C. 8:39-1.2

Adopted New Rule: N.J.A.C. 8:39-23.3

Standards for Licensure of Long-Term Care Facilities

Defibrillator

Proposed: June 6, 2005 at 37 N.J.R. 1932(a).

Adopted: October 14, 2005 by Fred M. Jacobs, M.D., J.D., Commissioner, Department of Health and Senior Services (with approval of the Health Care Administration Board).

Filed: October 20, 2005 as R.2005 d.400, **without change**.

Effective Date: November 21, 2005.

Expiration Date: August 20, 2006.

Summary of Public Comments and Agency Responses:

The public comment period ended August 5, 2005. The Department of Health and Senior Services (Department) received comments from the following:

1. Beth Ward, R.N., Assistant Executive Director, JNESO District Council 1 IUOE (International Union of Operating Engineers) AFL-CIO, New Brunswick, NJ; and

2. Susan R. Klein, R.N., M.S.N., Senior Vice President, Brandywine Senior Care, Mount Laurel, NJ.

The number in parentheses after each comment identifies the respective commenter listed above.

1. COMMENT: A commenter expresses her organization's support for the Department's proposal which would require a long-term care (LTC) facility to acquire and maintain a defibrillator on its premises and agrees that a sufficient number of staff should be trained in the use of the defibrillator at a facility's expense. (1)

RESPONSE: The Department thanks the commenter for her support of the proposal.

2. COMMENT: A commenter asks that the proposal ensure that facility staffing is sufficient to provide seven days, 24-hour availability of trained personnel, that staff on duty know who the trained person is on their shift, and that a facility be required to make provisions for staffing shortages such as sick calls, etc. (1)

RESPONSE: The Department does not believe that it is necessary that the rules dictate staffing requirements with the specificity suggested by the commenter. The Department believes that each facility is in the best position to determine how many staff members need to be trained in the use of defibrillators in order to meet staffing shortages, as well as deciding the best method to alert staff members as to who is trained in the use of the defibrillator. Each facility must ensure that its staffing is sufficient to meet the requirement at proposed N.J.A.C. 8:39-23.3(c) that at least one direct-care staff member on every shift be trained in CPR and the use of the defibrillator. Failure of a facility to comply with the requirements of N.J.A.C. 8:39-23.3 would constitute a deficiency pursuant to N.J.A.C. 8:39-3.1(b), which may subject a facility to any or all of the enforcement actions set forth in N.J.A.C. 8:43E.

3. COMMENT: A commenter asks that the importance of advanced directives and "do not resuscitate" orders be emphasized so that it is absolutely clear to staff which residents would not desire defibrillation. (1)

RESPONSE: The Department does not believe that it is necessary to address advanced directives and "do not resuscitate" (DNR) orders in proposed N.J.A.C. 8:39-23.3 as N.J.A.C. 8:39-9.6(g) already requires a facility to develop and implement policies to address applications of the facility's procedures for dealing with a resident with an advance directive who experiences an urgent life-threatening situation.

4. COMMENT: A commenter asks, since physician authorization is necessary for the purchase of an Automatic External Defibrillator (AED), if this authorization will be part of the cited regulations. (2)

RESPONSE: The Department has addressed the issue of physician authorization for the purchase of an AED by placing proposed N.J.A.C. 8:39-23.3, which would require a facility to maintain at least one defibrillator, in Subchapter 23, which addresses Mandatory Medical Services. The responsibility for the requirements of the new rule are, therefore, placed on a facility's medical director pursuant to N.J.A.C. 8:39-23.1. A facility's medical director will be the physician authorizing the purchase of a defibrillator.

5. COMMENT: A commenter asks if there are ongoing requirements for physician oversight, post-event review, and quality assurance programming. (2)

RESPONSE: A facility's medical director is responsible for coordinating medical care and directing the administrative aspects of medical care, pursuant to N.J.A.C. 8:39-23.1(a)1. Therefore, a facility's medical director is responsible for oversight, post-event review and quality assurance programming relating to the defibrillator. Many defibrillators come with data management software, so there will be no additional cost for quality assurance tools.

6. COMMENT: A commenter asks if a facility will be required to provide AED intervention for individuals other than residents and staff, that is, visitors and children. The commenter further asks how a facility's liability is addressed in this circumstance. (2)

RESPONSE: The issue of liability is not addressed within the proposed regulations and is, therefore, outside the scope of the proposal. The Department recommends that a facility concerned about liability regarding the use or non-use of a defibrillator discuss this matter with its legal counsel.

Absent a pre-existing duty to use a defibrillator, the rule amendment and new rule would not require a facility to intervene with a defibrillator for individuals other than residents. However, the Department hopes that a facility's trained medical staff would intervene with a defibrillator when appropriate.

In response to the commenter's question regarding liability, N.J.S.A. 2A:62A-27 provides for immunity from civil liability for the user of a defibrillator, who has successfully completed and holds current certification from a training program approved by the Department, and who renders emergency care in good faith. It is important to note that N.J.S.A. 2A:62A-26 requires the user of a defibrillator to have successfully completed and hold current certification from a training program in cardiopulmonary resuscitation and the use of a defibrillator that is recognized by the Department, in order for immunity to apply.

The immunity provisions of N.J.S.A. 2A:62A-27 also extend to the entity that acquired or provided a defibrillator and the prescribing licensed physician, so a long-term care facility and the medical director of a long-term care facility who have complied with the requirements of the proposed rules and N.J.S.A. 2A:62A-24 et seq., shall be immune from civil liability.

7. COMMENT: A commenter states that current standards require an AED to be retrievable within three minutes, and that many facilities, meeting only the one defibrillator in a central location requirement in proposed new N.J.A.C. 8:39-23.3 will not meet the three-minute standard. The commenter asks if there will be liability for facilities that do not meet the three-minute standard, or if these facilities will need to purchase additional AEDs. (2)

RESPONSE: Proposed N.J.A.C. 8:39-23.3, like its enabling statute N.J.S.A. 26:2H-12.26, does not establish a standard that requires a facility to maintain a defibrillator that is retrievable within three minutes. Both the proposed rule and the statute only mandate that a facility maintain at least one defibrillator in a central location.

8. COMMENT: A commenter states while the immediate cost of acquisition of an AED may not be a significant economic hardship for a facility, the ongoing maintenance, cost of replacement pads, training for staff, the cost of covering for staff members undergoing training, and the provision of certification materials/cards will have a substantial ongoing economic impact. The commenter further states while the regulations require only one trained staff member per shift, practicalities and legal ramifications dictate that licensed staff be trained. (2)

RESPONSE: The Department has attempted to minimize the staffing costs by requiring that a facility ensure that it has only one trained staff member per shift. The requirement that a defibrillator be obtained and properly maintained and that training be arranged and paid for employees of a nursing home and that the defibrillator is used by trained employees is mandated by statute at N.J.S.A. 26:2H-12.26. The National Center for Early Defibrillation estimates that accessories and consumables for an AED will total \$ 75.00 and maintenance costs will average \$ 100.00 annually. The commenter is correct that practicalities and legal ramifications may dictate that additional staff be trained. However, the rule amendment and new rule allow each facility to determine the number of trained staff to have on each shift beyond the minimum requirement of proposed N.J.A.C. 8:39-23.3 that one staff member be trained on every shift.

9. COMMENT: A commenter states that there are several organizations that offer AED and CPR training, such as the American Safety and Health Institute, which is less expensive than the training offered by the American Heart Association and American Red Cross and should be included on the list of providers. The commenter also inquires as to the manner in which facilities will access the list of approved providers. The commenter further asks that cost effective alternatives for training be identified and approved in order to decrease the economic impact on facilities, such as the combination of on-line didactic training and content testing in combination with in-person skills competency testing. The commenter inquires if there will be a mechanism to approve facilities that choose to develop their own training programs based on state of the art standards for validation of competencies. (2)

RESPONSE: While the proposed rule amendment and new rule are part of N.J.A.C. 8:39, Standards for Licensure of Long-Term Care Facilities, the approval of training courses is under the purview of the Office of Emergency Medical Services. Facilities seeking information on approved programs should contact the Office of Emergency Medical Services at (609) 633-7777.

Federal Standards Statement

A Federal standards statement is not required because the adopted amendment and adopted rule are not the subject of any Federal standards or requirements. The adopted amendment and adopted rule are required by State law, N.J.S.A. 26:2H-12.26.

Full text of the adoption follows:

8:39-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

. . .

"Defibrillator" means a medical device heart monitor and defibrillator that has received approval of its pre-market notification filed pursuant to 21 U.S.C. § 360(k) from the United States Food and Drug Administration, is capable of recognizing the presence or absence of ventricular fibrillation or rapid ventricular tachycardia, is capable of determining, without intervention by an operator, whether defibrillation should be performed, and upon determining that defibrillation should be performed, automatically charges and requests delivery of an electrical impulse to an individual's heart.

. . .

8:39-23.3 Defibrillator

(a) The facility shall maintain at least one defibrillator available to trained staff in a central location.

(b) The facility shall have a written protocol on the use of the defibrillator. The protocol shall address:

1. The testing and maintenance of the defibrillator according to the manufacturer's operational guidelines; and

2. The training of staff in the use of the defibrillator.

(c) The facility shall arrange and pay for the training of a sufficient number of direct-care staff in cardio-pulmonary resuscitation and the proper use of the defibrillator to ensure that at least one direct-care staff member on every shift holds a current certification from the American Red Cross, American Heart Association or other training program recognized by the Department in cardio-pulmonary resuscitation and the use of the defibrillator.

(d) The facility shall notify the appropriate first aid, ambulance or rescue squad or other appropriate emergency medical services provider of the type of defibrillator acquired and its location.